REMARKS

Claims 1-34 are present in this application and have been subjected to restriction by the Examiner under 35 U.S.C. §121 as follows:

> I. Claims 1-19, drawn to an isolated nucleic acid encoding a haemopoietin receptor, classified in class 536, subclass 23.5.
>
> II. Claims 20-27 and 30, drawn to an isolated haemopoietin receptor, classified in class 530, subclass 351.
>
> III. Claims 28-29, drawn to a method for modulating expression of NR6 in a mammal using a DNA encoding NR6, classified in class 514, subclass 44.
>
> IV. Claim 31, drawn to an antibody which specifically binds with a haemopoietin receptor, classified in class 530, subclass 387.1.
>
> V. Claims 32-34, drawn to a transgenic animal comprising a mutation in at least one allele of the gene encoding NR6, classified in class 800, subclass 21.

In support of the present restriction requirement, the Examiner has alleged that the subject matter defined by the claims of the present invention represents five separate and distinct inventions. The Examiner has further alleged that the subject matter of Groups I, II, IV and V are "independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility...". The Examiner alleges that the nucleic acids of Group I can be used, inter alia, to make hybridization probes; the protein of Group II can be used,

inter alia, as an immunogen to generate antibodies, and the antibody of Group IV can be used as a probe in immunoassays or in antibody-based therapies. The Examiner also alleges that the transgenic animal of Group V can be used to produce proteins which are "structurally and functionally different from the products of Groups I-II and IV." The Examiner has alleged that the inventions of Groups I and III are related as a product and process of use because the nucleic acid of Group I can also be used as, inter alia, a hybridization probe. Moreover, the Examiner has alleged that the inventions of Groups II-III and IV-V are unrelated because they are not capable of use together.

The Examiner admits, however, that the transgenic animal of Group V can be used to produce "large quantities of the protein in interest" and the antibody of Group IV can be used to obtain the nucleic acid of Group I.

As indicated, and in order to be fully responsive to the Examiner's requirements for restriction, Applicants provisionally elect, with traverse, to prosecute the subject matter of Group II, Claims 20-27 and 30, directed to an isolated haemopoietin receptor.

Pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. §121, first sentence (emphasis added).

The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized.

In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement. Group I, Claims 1-19, is directed to an isolated nucleic acid encoding a haemopoietin receptor of Group II. Group III, Claims 28-29, is directed to a method for modulating expression of the nucleic acid of Group I. Group IV is directed to an antibody which binds the haemopoietin receptor of Group II. Moreover, Group V is directed to a transgenic animal comprising a mutation of the nucleic acid of Group I

Furthermore, Groups I, II and III are related as a product and a method of using that product. These groups at the very least should be examined as a single invention. Clearly, all these embodiments define one single inventive

concept. Thus, Groups I-V are very clearly interrelated and interdependent, not "independent and distinct."

In addition, the courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the Applicant has done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicants' financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), Applicants are required to conduct simultaneous prosecution, as

here, requiring excessive filing costs or a compromise of the term of their patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that §121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle mbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986); and in Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990) that court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to

resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public's interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

The Examiner justified the restriction requirement in this case by reference to the different subclasses of the Patent and Trademark Office classification system in which the five groups of claims would allegedly be classed. This basis fails to justify the restriction requirement in this application.

Reliance on the classification of the groups of claims does not establish independence and distinctness. The classification system has no statutory recognition as evidence of whether inventions are independent and distinct. The classification system is instead an aid in finding and searching for patents.

The classification system is also an unreliable basis for requiring restriction between claims to the various aspects of applicant's unitary invention, because the system exhibits

considerable overlap in technical definitions. In particular, the definitions of subclasses in the classification system do not prevent the Examiner from basing patentability decisions, as to claims assigned to one group, on patent references found in the subclass(es) with which the Examiner associated another group of claims.

Furthermore, the classification system is a poor basis for requiring restriction between related aspects of an invention because classifications and definitions change over time. Thus, a classification that might have seemed to support restriction at a given time could change, thereby casting a shadow over the propriety of the restriction requirement later on during the term of the patents issuing from parent and divisional applications. Indeed, classifications seem largely to change in response to considerations of administrative convenience, and often in response to nothing more than growth in the number of patents in a given class or subclass. These considerations have nothing to do with whether the subject matter of patents assigned to different classifications is "independent and distinct" as those terms are used in 35 U.S.C. §121, which fact proves that basing restriction requirements on the classification system is improper.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement

for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,

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